UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,351	07/23/2001	Jeffrey M. Garibaldi	5236-000259	3404

7590 06/20/2003

Harness, Dickey & Pierce, P.L.C.
7700 Bonhomme, Suite 400
St. Louis, MI 63105

EXAMINER
SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
3762	7

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/911,351	Applicant(s) GARIBALDI ET AL.
	Examiner Kennedy Schaetzle	Art Unit 3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,16 and 17* is/are rejected.

7)☒ Claim(s) *9-15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 July 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "42" and "44" have both been used to designate the tether (note par. 0037). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "44" has been used to designate both tether and a stylet. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 26 (par. 0040), 46 and 48 (par. 0036). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Antecedent basis must be given for the subject matter of claims 6 and 7 where the medical device is recited as being an atherectomy tool or a flexible endoscope.

5. The disclosure is objected to because of the following informalities: paragraph 0037 refers to the magnetic bodies shown in Fig. 3A by reference numeral 40 rather than reference numeral 50 as is shown in the drawing; the third line of paragraph 0040 is grammatically awkward; the term "stylette" used throughout the specification appears to be a nonconventional spelling of the word "stylet."

Appropriate correction is required.

Election/Restrictions

6. The examiner notes the existence of several species (wherein the medical device is a pacing lead; wherein the medical device is a stent delivery system; wherein the medical device is a atherectomy tool; wherein the medical device is a flexible endoscope; the use of a stylet; the use of a guidewire; the use of a tether) but considers these species to be patentably indistinct from one another.

Claim Objections

7. Claims 3, 8, 11 and 15 are objected to because of the following informalities: in claims 3, 11 and 15, the term "stylette" appears to be a nonconventional spelling of the word "stylet"; in claim 8, the first occurrence of the word "the" on line 2 should be deleted; the definite article "the" should be inserted prior to the word "distal" on line 3. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

9. Claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Reference to the balloon in claim 16 lacks antecedent basis.

In claim 17, the reference to the magnet on the pacing lead is vague and indefinite as base claim 8 never recites that the pacing lead has a magnet thereon. It is unclear if it was the applicants' intent to base dependency on claim 16. When considering the claim on the merits, the examiner will assume dependency upon claim 17.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
> **(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent**

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Garibaldi et al. (Pat. No. 6,522,909).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Garibaldi et al. deploy coils 80 from the distal end of the magnetically guided catheter into the patient's vasculature as disclosed in col. 10, lines 7-24 and Fig. 8.

12. Claims 1, 2, 4 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Hall et al. (Pat. No. 6,292,678).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The elongated magnetic medical device may be magnetically navigated to the region of interest by a sheath 80, with a magnetic gradient additionally facilitating deployment of the medical device from the sheath as per col. 8, lines 21-41. The medical device may comprise electrodes for pacing the heart as per col. 6, lines 25-29. The examiner considers an elongated medical device with electrodes for pacing the heart to constitute a pacing lead.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstock et al. in view of Garibaldi et al. and Johnston et al..

One of the applied references has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Weinstock et al. disclose a method of implanting a pacing lead into the body comprising the basic steps of inserting a guidewire into the vasculature, sliding a delivery catheter over the guidewire, removing the guidewire, and inserting a pacing lead through the lumen of the delivery catheter for placement of the lead within the heart. Weinstock et al. do not disclose a method wherein the distal end of a guide

catheter is magnetically navigated into the target vessel. Garibaldi et al., however, teach that a magnetically guided catheter, guidewire, or other related device, allows for easy, fast and efficient navigation of medical apparatus in the body (note col. 2, lines 33-53). The use of a stylet to aid in the insertion of leads is old and well-known by artisans of ordinary skill, with the stylet being recognized as an obvious equivalent to the guidewire or tether (note the comments above under the "Election/Restrictions" heading). Artisan Johnston et al., for example, disclose the use of a magnetically controlled stylet to advance a pacing lead. Given the general method of implanting a pacing lead as disclosed by Weinstock et al., the teaching by Garibaldi et al. that magnetically navigated guide devices can significantly aid in the implant of medical devices, and the general knowledge that a stylet is simply another guide device that may be magnetically navigated as disclosed by artisan Johnston et al., those of ordinary skill in the art would have seen the obviousness of utilizing a magnetically navigated stylet in the invention of Weinstock et al..

Regarding claims 5-7, the particular form of the medical device deployed from the guiding catheter would have been considered an obvious application dependent parameter. In the general knowledge of the art, it is well-known that guide catheters may be employed to insert a wide variety of medical devices including stents, artherecotomy tools and endoscopes. Such equipment typically must be navigated through difficult and tortuous paths of the human body. To aid in their correct placement, those of ordinary skill in the art would have seen the obviousness of modifying the method disclosed by Weinstock et al., Garibaldi et al., or Johnston et al. to include such instruments. Again, attention is invited to the above paragraph concerning non-distinct species.

Allowable Subject Matter

15. Claims 9-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claim 10, although Hall et al. disclose the use of a tether with a magnetically responsive seed thereon for guiding a delivery catheter, there is no teaching in the art of record for modifying the method of Hall et al. to include the step of removing the seed from the lumen of the catheter with the tether when the distal end of the delivery catheter is in the desired location in the heart. The method of Hall et al. in contrast removes the seed from the lumen with a magnetic gradient when deploying the magnetic device, rather than pulling on the tether to remove the magnetic device from the body. Furthermore, while artisan Werp et al. utilize a magnetic seed on a tether to position a delivery catheter and subsequently a medical device, there is no suggestion for modifying the method of Hall et al.. It should be noted that the method of Werp et al. relates to the intraparenchymal positioning of medical devices.

Regarding claim 11, although Hall et al. disclose the use of a stylet, such a means is used to push the magnetic element out of the delivery catheter and is not recited as being used to navigate the catheter. Magnetic navigation of the catheter is performed by using the elongated magnetic element as discussed in col. 8, lines 25-28. Again, while the use of magnetic stylets in guiding catheters is old and well-known, there is no suggestion in the art for modifying the base reference to accommodate such a system.

Regarding claim 12, the use of the recited balloon in the method of Hall et al. is not taught in the prior art of record.

Regarding claim 13, since the examiner considers the elongated magnetic element with electrodes thereon to constitute a pacing lead as discussed *supra*, there is no suggestion in the art of record for modifying the method of Hall et al. to include the step of advancing the pacing lead or elongated magnetic element over a guidewire.

Likewise for claims 14 and 15, since the magnetic element of Hall et al. already has magnet material incorporated into it, it can be navigated to the desired site without the need for a magnetically controlled tether or stylet.

16. Claim 16 and 17 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Regarding claim 16, reasons for allowance parallel that given for claim 12.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is (703) 308-2211. The examiner can normally be reached on M-F from 9:30 - 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

KJS
June 13, 2003

KENNEDY SCHAETZLE
PRIMARY EXAMINER